Trial Description

Title

Exploration of the effect of a comprehensive, multidimensional living and care concept on people with dementia and nurses in stationary long-term care on the example of a dementia special care unit.
Subprojects: summative and formative evaluation

Trial Acronym

EvalD

URL of the trial

[---]*

Brief Summary in Lay Language

To facilitate a worthwhile life for people with dementia is an aspiration of many long-term care institutions. The promotion of quality of life and independence represents a challenge in nursing care, which is often stretched to its limit. Nowadays there exist many different models, which aim at improving the care of people with dementia.
In this study three different nursing homes are evaluated scientifically. The nursing care in a dementia special care unit is compared to two traditional nursing homes. The aim of the study is to explore how the dementia special care unit affects quality of life of residents with dementia in comparison to traditional nursing homes. Furthermore, the effect of the different care models on the strain in care is studied.
To reach the goal a written survey with residents with dementia and nurses is conducted. Nurses, who worked at the Institution for at least six month at the time of the survey are eligible to complete the questionnaire. The questionnaire will be distributed on the wards at the beginning and near the end of the study. The questionnaire contains questions about the strain in the care of people with dementia, the competence in care of people with dementia and the overall job satisfaction. Residents with dementia, who are newly moved into the nursing home, can participate in the survey, it they and their legal agents agree. The questionnaire will be filled out by trained nurses at three different dates: approximately one week, one month and six month after admission to the nursing home. The questionnaire is designed in such a way that nurses can fill it out by themselves and do not need to question the residents directly. The questions include dimensions such as quality of life, need for nursing care (functional abilities), cognition, agitation, sleep problems, apathy, medication and recent hospital admissions.
In addition, observations on all participating wards are conducted. The observations will take place on consecutive days, the focus lies on the residents with dementia and the people interacting with them.
Supplementary detailed information will be collected in interviews with nurses, managers and residents' family members. The observations and the interviews will give an insight on which interventions in the care of residents with dementia are used, how they affect residents and nurses, and in possible facilitators and barriers from different perspectives.

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Brief Summary in Scientific Language

Priority in health care for people with dementia is to improve or maintain their quality of life. To meet the challenges in the care of People with dementia, a complex living and care concept was established in a dementia Special care unit in a nursing home. The dementia special care unit should promote the quality of life of the residents with dementia through a care that is orientated at the needs of the residents. Furthermore, the nurses' strain in care for residents with dementia should be reduced.

The aim of the study is to evaluate theory-drivenly the comprehensive, multidimensional living and care concept of the dementia special care unit.

In the first phase of the project (subproject 1) a program theory of dementia special care units was developed, which illustrates the interventions and their effect mechanism and the deduced outcome indicators. In a participatory approach three perspectives on the dementia special care unit were subsumed: the perspective of the developers of the dementia special care unit, the perspective of the nurses working there and the perspective of the current scientific literature. Therefore, a literature review and three workshops with developers and nurses were conducted.

In the second phase of the project the effect of the dementia special care unit is examined using the outcome indicators derived using the program theory. For this purpose, a summative evaluation with a quasi-experimental multiple groups design is realized (subproject 2). An accompanying formative evaluation (subproject 3) is further informing about the implementation of the care concept, program fidelity, facilitating and hindering factors and can support the interpretation of the results of the summative evaluation. Part of this registration are subproject 2 and 3 - the summative and formative evaluation of the dementia special care unit.

For the summative evaluation (subproject 2), which is used to examine the effects of the dementia special care unit, a written survey is conducted. The outcome indicators derived from the program theory refer to residents and nurses. Questionnaires for nurses include the outcome indicators job satisfaction, strain in care, nursing competence in the care for people with dementia and person-centeredness in nursing. Questionnaires for residents contain the following domains: quality of life, behavioural and psychological symptoms of dementia, psychotropic medication, cognitive impairments, severity of dementia, functional abilities and needs for care. Nurses fill out the questionnaires on their own. Residents' data is collected in a proxy-survey, filled out by trained nurses.

The intervention group consists of nurses and newly moved in residents of the dementia special care unit. The control groups consist of nurses and newly moved in residents with dementia of two nursing homes without a dementia special care unit.

Data analysis is conducted with the methods of descriptive and inference statistics.

The formative evaluation (subproject 3) is used to examine program fidelity. The analyses will provide conclusion on why or why not the intervention works. Furthermore, facilitating and hindering context factors and adoptions of the intervention should be identified and it should be examined whether and which additional interventions outside the program theory have been implemented and whether and which unexpected effects could be found.

For the formative evaluation, directly and passively participating and open observations and qualitative, semi-structured interviews with stakeholder are realized.

The observations are taking place in all participating units of the intervention and control groups.

Qualitative interviews are held with nurses, family members of the residents, members of the management of the nursing homes of the intervention and control groups. Content analysis will be used as data analysis method for observations

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and interviews.

Organizational Data

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- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **16-024 , Ethikkommission der deutschen Gesellschaft für Pflegewissenschaft**

Secondary IDs

Health condition or Problem studied

- Free text: **Demenz**
- ICD10: **F00 - Dementia in Alzheimer disease**
- ICD10: **F02 - Dementia in other diseases classified elsewhere**
- ICD10: **F03 - Unspecified dementia**
- ICD10: **F01 - Vascular dementia**

Interventions/Observational Groups

- Arm 1: **Residents and nurses of the dementia special care unit - intervention group A:
  The intervention consists of the comprehensive and complex living and care concept of the dementia special care unit:
  - architecture: separate ward for residents with dementia, logical space syntax, circular construction, colour, light and material concept, direct garden access, small home-like wards à 10 residents
  - non-pharmacological interventions as first-line therapy for behavioural and psychological symptoms of dementia: validation (N. Feil), Snoezelen, person-centred care, biographical work
  - staff: increased staff to resident ratio, specifically trained staff (e.g.: validation)**
- Arm 2: **Residents with dementia and nurses of the nursing home in control group B: Control group B represents a traditional nursing home, which established some interventions for residents with dementia in a specific project:
  - architecture: shared ward for residents with and without dementia, tubular construction, reminiscence niches, wards à 42 residents**

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- **handling of behavioural and psychological symptoms of dementia: primary nursing, biographical work, validation (which is rarely used)**
- staff: regular staff to resident ratio, staff trainings in primary nursing

- ■ Arm 3: **Residents with dementia and nurses of the nursing home in control group C: Control group C represents a traditional nursing home, which has not implemented systematically any intervention for residents with dementia:**
- architecture: shared ward for residents with and without dementia, tubular construction, wards à 42 residents
- handling of behavioural and psychological symptoms of dementia: no systematic approach throughout the nursing home
- staff: regular staff to resident ratio, regular staff trainings, no specific focus on dementia in the trainings

Characteristics

- ■ Study Type: **Interventional**

- ■ Study Type Non-Interventional: **[---]***

- ■ Allocation: **Non-randomized controlled trial**

- ■ Blinding: **[---]***

- ■ Who is blinded: **[---]***

- ■ Control: **Active control (effective treament of control group)**

- ■ Purpose: **Other**

- ■ Assignment: **Parallel**

- ■ Phase: **N/A**

- ■ Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Quality of life of nursing home residents with dementia: examined with the QUALIDEM (Ettema et al., 2007) at three timepoints: 1 week, 1 month and 6 months after the residents moved into the nursing home

Secondary Outcome

Nurses' strain in care: examined with the Strain in Dementia Care Scale (Edberg et al., 2015) at two timepoints: at the beginning and at the end of data collection

Countries of recruitment

- ■ AT **Austria**

Locations of Recruitment

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■ other **Pflegeheime - nursing homes, Grafenwörth, Pöchlarn, Pressbaum - Austria**

Recruitment

■ Planned/Actual: **Actual**

■ (Anticipated or Actual) Date of First Enrollment: **2017/02/01**

■ Target Sample Size: **400**

■ Monocenter/Multicenter trial: **Multicenter trial**

■ National/International: **National**

Inclusion Criteria

■ Gender: **Both, male and female**

■ Minimum Age: **no minimum age**

■ Maximum Age: **no maximum age**

Additional Inclusion Criteria

Residents: MMSE<24, moved into the nursing home since the beginning of the trial
nurses: worked at the nursing home for a minimum of six month at the time of the survey

Exclusion criteria

Residents: MMSE>23, residents who already lived in the nursing home at the beginning of the trial
nurses: worked at the nursing home less than six month at the time of the survey, temporary workers, trainees and apprentices

Addresses

■ **Primary Sponsor**

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Alser Straße 23/12
1080 Wien
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■ **Contact for Scientific Queries**

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URL: **[---]***

Sources of Monetary or Material Support

■ **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

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Capistrangasse 5
1060 Wien
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E-mail: **[---]***
URL: **[---]***

Status

■ Recruitment Status: **Recruiting complete, follow-up continuing**

■ Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

* This entry means the parameter is not applicable or has not been set.

*** This entry means that data is not displayed due to insufficient data privacy clearing.

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